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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/593,417 | 06/14/2000 | Raymond Andersen | 108281-00001 | 8238 |

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09/12/2002

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| EXAMINER |
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LUKTON, DAVID

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| ART UNIT | PAPER NUMBER |
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1653

DATE MAILED: 09/12/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/593,417

Applicant(s)
Andersen

Examiner
David Lukton

Art Unit
1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 2, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 8-12 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 8-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Pursuant to the directives of paper No. 9 (filed 2/27/02), claims 5-7 have been cancelled, and claims 8-12 added. Claims 1-4, 8-12 are pending.

Applicants' election of compound #2 in table 4 (page 52) is acknowledged.

*

The specification is objected to.

Applicants are reminded of the preferred arrangement of the specification:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (i) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

Applicants should provide the following section heading, where appropriate:

DETAILED DESCRIPTION OF THE INVENTION.

Also, a figure legend should be created and placed just before the "DETAILED DESCRIPTION OF THE INVENTION", and the following heading provided just before that:

BRIEF DESCRIPTION OF THE DRAWINGS

In addition, an abstract is required, and does not appear to have been submitted.

With respect to a matter unrelated to the foregoing, the vertical lines in table 2 (page 24)

are not fully legible. In addition, in table 4 (pp. 52-53, not all of the atoms are fully legible. For example, the nitrogen atom which is beta to the indole group is not fully visible. The printer has authority in this matter.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 9 is drawn to a "pharmaceutical composition", and moreover, explicitly recites the phrase "for treating cancer". However, enablement for this is lacking.

Applicants have provided in vitro data which shows growth inhibition of carcinoma cells and of leukemia cells. It is stipulated that such growth inhibition will occur *in vivo* as well. However, treatment of cancer is another matter altogether. As applicants may be aware, there are vast numbers of compounds which are cytotoxic to tumor cells in vitro, yet which are not effective to bring relief to patients stricken with cancer. While there have been some successes in the treatment of cancer using cytotoxic agents,

successes have been few and far between. As it happens, "undue experimentation" would be required to practice the claimed invention. Either of the following is suggested:

A composition comprising a compound according to claim 1 in combination with a pharmaceutically acceptable carrier.

A composition comprising a pharmaceutically acceptable carrier together with a compound according to claim 1 in an amount effective to inhibit growth of tumor cells.

*

The following is a quotation of the appropriate paragraphs of 35 U.S.C §102 that form the basis for the rejections under this section made in this action.

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2) and (4) of section 371(c) of this title before the invention thereof by the applicant for the patent.

Claim 1 is rejected under 35 U.S.C. §102(e) as being anticipated by Bogden (USP 5,736,517).

Bogden teaches numerous peptides (e.g., col 4, line 57+) containing tryptophan for

treating cancer. The cited claims encompass tryptophan-containing peptides if the substituent variables correspond as follows:

n = 0
R1 = H
R73 = H
R6 = H
R2 = substituted alkyl
R72 = H
R70 = H
R71 = substituted alkyl
R74 = H
R3 = H or substituted alkyl
R7 = H
R75 = substituted alkyl

Thus, the claim is anticipated.

✱

Claim 1 is rejected under 35 U.S.C. §102(a) as being anticipated by Crews (*J. Org. Chem.* **59**, 2932, 1994).

Crews discloses the compound designated milnamide A. This corresponds to a compound within the genus of instant claim 1 as follows:

R6 = a methine group bonded to the indole group, forming a 6-membered ring;
R1 = methyl
R75 = -CH(iPr)-CH=CH(Me)-COOH

Thus, the claim is anticipated.

✱

The following is a quotation of 35 USC §103 which forms the basis for all obviousness rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claim 1 is rejected under 35 U.S.C. §103 as being unpatentable over Kashman (USP 5,661,175).

Kashman teaches the use of hemiasterlin for treating cancer. Claim 1 precludes the possibility of R¹ being methyl if the other substituents correspond as indicated.

However, there are dozens of "obvious variants" that are not excluded. For example, the compound in which R¹ is ethyl (instead of methyl) is not excluded. N-methyl amines are generally obvious over N-ethylamines, and *vice versa*. One of ordinary skill considering the Kashman reference would expect that the N-ethyl homolog would exhibit substantially the same activity. Similarly, the compound in which R⁶ is ethyl would not be excluded.

The claim is rendered obvious.



It is noted that a vertical line passes through all of the pages of paper No. 9 (filed 2/27/02). The persons responsible for printing the final document may question the meaning of this line. Accordingly, prior to issuance of a notice of allowance, a new copy of each claim (without the vertical line) should be provided for each claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800